UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,639	02/01/2001	Steven M. Ruben	PZ013P1C1	8758

22195 7590 06/26/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	8

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/774,639	Applicant(s) RUBEN ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, 14, 15 and 21, drawn to nucleic acids, vectors, host cells and methods of synthesizing proteins using said host cells, classified in Class 435, subclass 69.1, 252.3 and 320.1, and Class 536, subclass 23.5.

II. Claims 11, 12, and 16, drawn to proteins, classified in Class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in Class 530, subclass 387.

IV. Claims 17, drawn to methods of treatment using a polynucleotide, classified in Class 514, subclass 44.

V. Claim 18, drawn to methods to detect a mutation in a polynucleotide, classified in Class 435, subclass 6.

VI. Claim 19, drawn to a method to a method of diagnosis by detecting a protein, classified in Class 435, subclass 7.1.

VII. Claim 20, drawn to a method for identifying compounds which bind to a protein, classified in Class 435, subclass 7.1.

VIII. Claims 22, drawn to a method of determining the activity of a protein, classified in Class 435, subclasses 4 and 7.1.

IX. Claim 23, drawn to a binding partner, classified in Class 514, subclass 2.

X. Claim 24, drawn to a method of treatment comprising administering a protein, classified in Class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas invention II is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the antibodies of invention III. Furthermore, the different inventions are not disclosed as capable of use together and have different functions and have different physical and structural properties.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for diagnostic methods.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

Inventions I and VI, I and VII , I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to practice the methods of inventions VI, VII or X.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids, or for therapeutic or diagnostic methods.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are structurally and functionally distinct from the binding partners of invention IX. Furthermore, the different inventions are not disclosed as capable of use together and are utilized in different methods, such that the nucleic acids of invention I may be used in methods of diagnosis and the binding partners of invention IX may be used in therapeutic methods.

Inventions II and III are patentably distinct in structure in that the proteins of invention II have a different amino acid sequence and 3-dimensional structure as compared to the antibodies of invention III. Furthermore, the products of invention II and III are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention II since the antibodies of invention III can be isolated from natural sources.

Inventions II and IV, II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to practice the methods of inventions IV or V.

Inventions II and VI and II and VII, II and VIII, and II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating antibodies.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different functions and different modes of operation. Further, the proteins of invention II and the binding partners of invention IX are structurally distinct.

Inventions III and IV, III and V, III and VIII, and III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the methods of invention IV, V, VII or X.

Inventions III and VI and III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic uses.

Inventions III and VII are drawn to patentably distinct inventions. Invention III is drawn to an antibody, whereas invention VII is generically drawn to any compound which binds the stated proteins. Antibodies are composed of a specific amino acid sequence and have a unique structure and defined interaction with a protein, whereas the compounds of invention VII include any type of chemical moiety having any structural or functional properties.

Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for detecting or isolating proteins.

Inventions IV, V, VI, VII, VIII and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions IX and IV, IX and V, IX and VI, IX and VIII, IX and X are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of use together because the binding partner of invention IX is not required to practice the methods of inventions IV, V, VI, VIII, or X.

Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the binding partners of invention VII can be used in a materially different process, such as for therapeutic purposes.

2. ***Sequence Election Requirement Applicable to All Groups***

Each invention detailed above reads on a patentably distinct invention drawn to distinct sequences. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each invention. For an elected invention drawn to a nucleic acid or amino acid sequences, Applicants must further elect a <u>single</u> nucleic acid or amino acid sequence. For example, if Applicant elects invention I, Applicant must further

elect a single nucleic acid sequence "X", a single nucleic acid encoding protein "Y" and a single cDNA contained in a clone "Z".

It is noted that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

June 18, 2002

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER